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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,352	11/01/2001	Christof Westenfelder	10402/15	5227

7590 12/12/2003

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EXAMINER	
SCHNIZER, HOLLY G	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/003,352	WESTENFELDER, CHRISTOF	
	Examiner	Art Unit	
	Holly Schnizer	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) ~~Paper No(s)~~ FILED 1·25·02 6·24·03
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims

Claims 1-11 are pending and have been considered on the merits in this Office Action.

Information Disclosure Statement

The Information Disclosure Statements filed January 25, 2002 and June 24, 2003 have been considered and an initialed copy is attached to this Office Action. The examiner notes that the listing of references in the specification on pages 22-24 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references are initialed on the Form PTO-1449 or have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The Examiner points out that page 3 of the Specification refers to reference "[22]" (line 8) and "[23]" (line 12) yet there are only 20 references listed on pages 22-23 of the Specification. Therefore, the citation of "[22]" and "[23]" appear to have no meaning. The examiner suggests deleting these citations from the Specification.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Westenfelder et al. (J. Am. Soc. Nephrol. Sept. 2000) 11: 597A, abstract A3148; ref. B6 of IDS filed June 24, 2003).

Westenfelder et al. teach a method of treating ischemic acute renal failure by administering a composition comprising EPO and a pharmaceutically acceptable carrier. Westenfelder et al. state that EPO administration ameliorated the decline in renal function (prevented any further decline in renal function; see clm. 1) and accelerated functional recovery. Westenfelder et al. state that EPO acts as a mitogen and motogen for renal tubular cells. The EPO administered was contained in a pharmaceutically acceptable diluent and was administered systemically at 300 U/kg, 2-4 times, 24 hours apart (see 5th line from bottom). Since the EPO administered had an identical structure and function to that of recombinant EPO, the EPO used in the Westenfelder et al. method is not patentably distinguishable from recombinant EPO.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Nemoto et al. (J. Am. Soc. Nephrol. (2000) 11: 594A, abstract A3134; ref. B1 of IDS filed June 24, 2003).

Nemoto et al. teach a method of preventing and treating ischemic acute renal failure by administering a composition comprising EPO and a pharmaceutically

acceptable carrier. It is noted that with respect to present claims 1 and 3, "preventing" is treated here as meaning treating so as to delay or ameliorate acute renal failure (e.g. preventing further decline in renal function). Nemoto et al. disclose that there was a systemic response to the administration of EPO. EPO treatment led to an increase in hematocrit. Prevention of cell apoptosis in renal tubular cells and stimulation of motogenesis and mitogenesis in renal tubular cells are inherent properties of EPO that would have occurred after administration of EPO. The EPO administered was contained in pharmaceutically acceptable diluents (saline) and, since the EPO administered had the same function and structure as recombinant EPO, the EPO used in the method of Westenfelder et al. is not patentably distinguishable from recombinant EPO.

Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Westenfelder et al.(J. Am Soc. Nephrol. (2001) 12: 739A; ref. B4 of IDS filed June 24, 2003).

Westenfelder et al. teach a method of preventing and treating ischemic acute renal failure by administering a composition comprising EPO and a pharmaceutically acceptable carrier. Westenfelder et al. disclose that the EPO treatment was significantly renoprotective when administered pre-ARF and had a significant recovery stimulating effect when administered after induction of severe ARF. Westenfelder et al. report that the administration of EPO elicited an anti-apoptotic motogenic and mitogenic response in tubular cells. The EPO administered was contained in pharmaceutically

acceptable diluents and, since the EPO administered had the same function and structure as recombinant EPO, the EPO used in the method of Westenfelder et al. is not patentably distinguishable from recombinant EPO.

Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Westenfelder et al. (J. Invest. Med. (Jan. 2001) 49(1): 59A, abstract 319; ref. B5 of IDS filed June 24, 2003).

Westenfelder et al. teach a method of preventing and treating ischemic acute renal failure by administering a composition comprising EPO and a pharmaceutically acceptable carrier. Westenfelder et al. conclude that EPO administration ameliorated the decline in renal function and accelerated functional recovery. It is noted that with respect to present claims 1 and 3, "preventing" is treated here as meaning treating so as to delay or ameliorate acute renal failure (e.g. preventing further decline in renal function). Prevention of harmful cell apoptosis in renal tubular cells, stimulation of motogenesis and mitogenesis in renal tubular cells are inherent properties of the EPO and would have occurred upon administration of the EPO. The EPO administered was contained in pharmaceutically acceptable diluents and, since the EPO administered had the same function and structure as recombinant EPO, the EPO used in the method of Westenfelder et al. is not patentably distinguishable from recombinant EPO.

Claims 2-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Nemoto et al. (Kidney Intl. (Jan. 2001) 59: 246-251; ref. B2 of IDS filed June 24, 2003).

Nemoto et al. teach a method of treating ischemic acute renal failure by systemic administration of a therapeutically effective amount of recombinant erythropoietin (EPO) and a pharmaceutically acceptable carrier (saline) (p. 246-247, "Methods"). Nemoto et al. state that EPO may change the course of tubular repair. Prevention of harmful cell apoptosis in renal tubular cells and stimulation of motogenesis and mitogenesis in renal tubular cells is an inherent activity of EPO and would have occurred upon administration of EPO.

Conclusions

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached Tuesday, Thursday, and Friday from 8 am to 5:30 pm. ***The examiner has been tentatively scheduled to move to the new Office on January 8, 2004. After the move, the examiner may be reached at (571) 272-0958.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703 308-0196.

Holly Schnizer
December 6, 2003

CHRISTOPHER S. F. LOW
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